



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 14, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-40

Stephen Wurster, President/Owner
Buns Master Bakery, Inc.
7304 Lakewood Drive West
Lakewood, Washington 98499

WARNING LETTER

Dear Mr. Wurster:

The Food and Drug Administration (FDA) conducted an inspection of your bakery located at 7304 Lakewood Drive West, Lakewood, Washington, on April 21-22, 2004. The inspection revealed deviations from the Current Good Manufacturing Practice (CGMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110), and Food Labeling regulations, 21 CFR Part 101. These conditions cause the bakery products manufactured in your facility to be adulterated and misbranded under Section 402(a)(4), 403(e)(2), and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and regulations through links in FDA's homepage at www.fda.gov.

At the conclusion of the inspection, you were issued Form FDA-483 which delineated a number of significant unsanitary conditions present at your facility at the time of the inspection. These conditions, several of which were previously brought to your attention during the 2002 and 2003 inspections, cause products manufactured in your facility to be adulterated under Section 402(a)(4) of the Act. Objectionable conditions observed include the following:

- Failure to exclude pests from the food plant [21 CFR 110.35(c)]. Specifically,
 - Thirteen rodent pellets were observed behind a rack of flour in the SW corner of the dry ingredient storage area.
 - One dead and three live beetles were observed on the ledge on both sides of the belt on the pizza sheeter in the processing area.
 - One live beetle was observed behind the roller on the back side of the pizza sheeter machine.
 - Thirty-eight beetles were observed along the ledge in the motor housing area of the pizza sheeter machine.

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- Failure to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing [21 CFR 110.80(b)(1)]. Specifically,
 - After clean-up and prior to production, residual dough from the previous production day was found on the [REDACTED] mixer blade and bowl, on the hopper of the busse machine, and under the belt of the [REDACTED] machine; old product residual was found inside the cups of the Kaiser-Vienna Roll press.
 - After clean-up and just prior to production, one dead and two live beetles were observed on the ledge on both sides of the belt on the pizza sheeter in the processing area.
- Failure to take necessary precautions to ensure persons working in direct contact with food conform to hygienic practices to protect against contamination of food [21 CFR 110.10(b)(3)]. Specifically,
 - An employee was observed using her hands to move a garbage can around the production area then immediately touching raw dough without first washing and sanitizing her hands.
 - An employee was observed handling the bottom surface of the containers while carrying them from the walk-in cooler to the production room and then immediately touching raw dough without first washing and sanitizing her hands.
 - An employee was observed touching her hair under her hair net and then immediately touching raw dough without first washing and sanitizing her hands.

In addition, your Buns Master Cheese Stick product is misbranded under section 403(i)(2) of the Act in that the label does not declare the sub-ingredients of cheddar cheese, enriched wheat flour, or vegetable shortening as specified in 21 CFR 101.4(b)(2). These are multi-component ingredients, in other words, ingredients that themselves contain two or more ingredients; however, the ingredient statement does not include the common or usual names of the components of these ingredients.

This product is further misbranded under Section 403(e)(2) of the Act in that the label fails to declare an accurate statement of the quantity of content in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, as required by 21 CFR 101.105.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with the applicable statutes and regulations enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We also note that the vegetable oil shortening ingredient does not specify the specific common or usual names of the individual fat and/or oil ingredients in the shortening [e.g., Vegetable shortening (soybean and cottonseed oil)], as required by 21 CFR 101.4(b)(14).

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Moreover, your Buns Master Cheese Sticks product label does not bear a "Nutrition Facts" statement, as required by 21 CFR 101.9(a), and you have not filed for a claimed exemption with the FDA. If you employ fewer than an average of 100 full-time equivalent employees, and have sold fewer than 100,000 units of each product within the last 12 months, you may be eligible to claim an exemption from nutrition labeling under 21 CFR 101.9(j)(18). To claim this exemption, follow the procedure outlined in 21 CFR 101.9(j)(18)(ii) and (iv), located on page 45 at <http://www.cfsan.fda.gov/~lrd/CFR101-9.HTML>.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer, at (425) 483-4913.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483
21 CFR PART 110
Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement